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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/499,765 02/08/00 HAYASHI

Y 46910-DIV2

EXAMINER

HM12/1019

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NOLAN, P

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
**09/499,765**

Applicant(s)  
**Hayashi et al.**

Examiner  
**Patrick J. Nolan**

Art Unit  
**1644**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jul 29, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14, 16-19, and 25 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 16-19, and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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**Part III DETAILED ACTION**

1. This application is a divisional of 09/076,938 which is divisional of 08/736,434.

2. Claims 14 and 16-19 and newly added claim 25 are pending.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 14, 16-19 and newly added claim 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons cited in Paper No.7.

Applicant's arguments filed 7-29-01 have been fully considered but are not found persuasive.

Applicant argues that the Textbook entitled IMMUNOLOGY clearly demonstrates that very large doses of antigen often result in specific T-and sometimes B-cell tolerance and thus one of ordinary skill in the art would recognize that identification and administration of an autoantigen can easily lead to immunotolerance.

However, as clearly discussed in Paper No. 6, tolerance to one antigen does not usually treat ongoing autoimmune diseases because usually the autoimmune disease is caused by multiple antigens and Wraith et al., (V, Cell 59: 247-255, 1989) teach the "Inhibition of the response restricted by one class II molecule may lead only to the escape to an autoimmune response to a separate epitope restricted by a different class II molecule." (page 253 column 1, in particular). In other words, the tolerization of an immune response to one antigen is not likely to treat a multi-faceted autoimmune response. Furthermore, Applicant appears to misrepresenting the teachings of the Immunology text. The teachings are clearly limited to induction of immunotolerance in neonatal mice which have immature immune systems and are much more subject to immune manipulation than an individual with a fully mature competent immune system.

Applicant argues that one of skill in the art could easily obtain immunochemically fragments useful in their treatment methods by following the teachings of the specification.

However, they provide no reference supporting their position. In rebuttal to Applicant's assertion that one of skill in the art could easily determine immunochemically fragments useful in their treatment methods by following the teachings of the specification, Applicant is invited to consider Karin et al., which demonstrates that a substitution of a phenylalanine with alanine (i.e. a conservative amino acid substitution) at position 89 resulted in an increase in T cell proliferation, binding affinity of the peptide and induction of EAE in rats, while the same amino acid substitution, a phenylalanine for an alanine, at position 90, resulted in the exact opposite results, decreased binding, T cell proliferation and no induction of EAE (see Table 1, in particular). What the results of the Karin et al., article indicate is that the effects of amino acid changes on peptide-MHC binding, T cell proliferation and in vivo effects of said peptides is unpredictable. Since Applicant has provided little guidance in their specification as to how one of skill in the art would overcome such unpredictability of the effects amino acid changes have on the peptides, it would require an undue of experimentation to practice Applicant's claimed invention.

Applicant argues that they have provided experimental data demonstrating the effectiveness of the treatment regimen on mice which already have established SS.

However, Application information is not supplied in the form of a declaration. Furthermore, it is not clear that the experiments performed were done in accordance to the teachings of the specification. Substantially the same is not sufficient. Lastly, the fragment being used in the experiments, it is not clear it is the same as disclosed in the specification.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

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7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
October 18, 2001